

**REMARKS**

Applicants thank the Examiner for the thorough consideration given the present application. Claims 1-59 are currently being prosecuted. The Examiner is respectfully requested to reconsider his rejection in view of the amendments and remarks as set forth below.

Information Disclosure Statement

As discussed in the February 6, 2004 Reply, it is noted that Information Disclosure Statements were submitted in the above-identified application on August 3, 2001 and September 28, 2001. While the Examiner has returned an initialed copy from the August 3, 2001 Information Disclosure Statement, such an initialed PTO-1449 form has not been returned for the September 28, 2001 Information Disclosure Statement. Again, notification of receipt of the September 28, 2001 Information Disclosure Statement, as well as consideration of all the documents cited therein, are respectfully requested.

Entry of Amendments

It is respectfully requested that the present Amendment should be entered into the official file, in view of the fact that the amendments to the claims automatically place the application in condition for allowance. Therefore, entry of the Amendment is requested, since the only changes that are being presented are

those required by the Examiner to overcome objections due to informalities. Accordingly, entry and full consideration of the present Amendments are considered appropriate.

Allowable Subject Matter

It is gratefully acknowledged that the Examiner considers the subject matter of claims 1-6, 8-21, 23-29 and 49-56 as being allowable, and the subject matter of claims 7, 22, 31, 32, 35, 36, 40 and 42 as being allowable if formal matters are overcome. Claims 7 and 22 have been amended to overcome their informalities. The remaining claims remain objectionable as depending from a non-allowed independent claim. These claims have not yet been rewritten in independent form, because it is believed that claim 30 from which they depend is allowable.

Objection to the Claims

The Examiner objected to claims 7, 22, 30 and 45-47 due to informalities. In regard to claims 7, 22 and 30, Applicants have corrected the spelling of the word "assess." In regard to claims 45-47, the phrase "by means of" has been changed to "using." Accordingly, this objection is believed to be overcome.

Rejection under 35 USC 103

Claims 30, 33, 34, 37, 39, 41, 43-48 and 57-59 stand rejected under 35 USC 103 as being obvious over SHAFFER et al. (U.S. Patent 5,429,123). This rejection is respectfully traversed.

The Examiner states that the SHAFFER et al. reference uses a system with a gas blender, two gas sources, an oxygen saturation measuring device, and a second detection means for measuring inspired oxygen. Applicants submit that claim 30 is not obvious over this reference.

In response to Applicants' previous argument, the Examiner has directed attention to column 3, lines 13-20, where the Examiner states a scheme to predict the needed oxygen level is disclosed. Applicants have reviewed this section and disagree that any prediction is provided therein. In this paragraph, the scheme described is where an actual oxygenation level is measured by a sensor, and the difference between the measured level and a reference level is detected as an error in an analyzer. If an error is present in the oxygenation level, information about the error is transmitted to a CPU, which adjusts the ventilation system accordingly to remove the error. Thus, this does not disclose a predicting scheme, but rather a control system with a feedback mechanism. Accordingly, Applicants submit that the Examiner is incorrect that this reference teaches a scheme for predicting a possible response of the patient to a change in the inspired gas for a fast diagnostic result to be reached with a minimum number of

measurements. Accordingly, Applicants submit that claim 30 is not obvious over this reference.

Further, it is noted that the final paragraph of claim 30 specifically requires that the computer retrieves and stores a first measurement which is the concurrent output produced by the dual detection means. The stored outputs are mutually related and are stored in a data storage associated with the computer. Applicants submit that this operation is not shown in the SHAFFER et al. reference. Instead, the information is used to immediately adjust the ventilation process rather than being stored in a data storage. Further, Applicants submit that the Examiner has not even alleged that this procedure is obvious and, accordingly, Applicants submit that the Examiner has not met his burden of showing an obviousness rejection.

Claim 30 includes a step for inserting the appropriate change in oxygen level in the inspired gas from the current oxygen level, so as to achieve a given desired target oxygen level in the blood. Thus, a prediction is made of a possible response of the patient to a change in the inspired gas for a fast diagnostic result to be reached with a minimal number of measurements. There is, however, no motivation or suggested in SCHAFFER et al. for one skilled in the art to adopt such a prediction scheme as the heliox ventilation conditions are monitored continuously and adjusted instantaneously using the feedback mechanism as described in column 17, lines 46-51. The expectation of success is also doubtful by using

predictions instead of actual measurements as this would be hazardous to the patient. This is due to the fact that the heliox ventilation system requires high safety precautions as only a few breathing cycles with inappropriate respiratory parameters can be lethal to the patient. This is discussed in column 2, lines 15-29 of the patent.

In the embodiment of Figs. 8-10, for example, where the inspired oxygen fraction ( $F_{I_{O_2}}$ ) in step E to F is adjusted by predictions of the most probable effect on the arterial oxygen saturation ( $Sp_{O_2}/Sa_{O_2}$ ), preferably within a 90% certainty interval. Such a scheme of forecasting diagnostic results would not be obvious to implant in the SCHAFFER et al. arrangement due to the high safety precautions described in this reference. It is respectfully submitted that claim 30 is not suggested or rendered obvious by the SCHAFFER et al. teaching. Accordingly, Applicants submit that claim 30 is not obvious over this reference.

Furthermore, Applicants submit that claims 30-48 and 57-59, which depend from claim 30, are also considered to be allowable. In addition, these claims recite other features of the invention, some of which have already been indicated as being allowable by the Examiner.

#### Conclusion

In view of the above remarks, it is believed that the claims clearly distinguish over the patent relied upon by the Examiner. In

view of this, reconsideration of the rejections and allowance of all claims are respectfully requested.

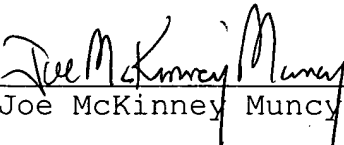
In the event the Examiner does not consider this application to be in condition for allowance, it is respectfully requested that this Amendment be entered for the purposes of Appeal. This Amendment should overcome the current grounds of rejection and therefore simplify the issues for Appeal. Nonetheless, it should be unnecessary to proceed to Appeal because the instant application should now be in condition for allowance.

In the event that any outstanding matters remain in this application, the Examiner is invited to contact the undersigned at (703) 205-8000 in the Washington, D.C. area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s)